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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,144	03/27/2001	Richard M. Terek	21486-021DIV	3262

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EXAMINER	
SANG, HONG	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 01/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/819,144	TEREK, RICHARD M.	
	Examiner	Art Unit	
	Hong Sang	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/25/01 & 9/29/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

RE: Terek

1. The preliminary amendment filed on 3/27/2001 is acknowledged. Claims 1-6 and 11-20 are canceled.

2. Claims 7-10 are pending and under examination.

3. The information disclosure statements (IDS) filed on 7/25/2001 and 9/29/2003 have been considered. Signed copies are attached hereto.

Specification

4. The first line of the specification should be updated if applicant desires priority under 35 U.S.C. 1 19(e), 120, 121 and 3654c) based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application (s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No.___" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date 6f the parent application.

For additional information, see United States Patent and Trademark Office OG Notices: 1268 OG 89 (18 March 2003) "Benefit of Prior-Filed Application".

Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7-10 are rejected as vague and indefinite for reciting the term "CSA" in claim 7 and "CSA-1" in claim 8 as the sole means of identifying the claimed molecules. The use of laboratory designations only to identify a particular molecule renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct molecules. The rejection can be obviated by amending the claims to specifically and uniquely identify CSA and CSA-1, for example, by SEQ ID NO.

Claim Rejections - 35 USC § 112, 1st paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 8-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in In re Wands, 8 USPQ2d 1400 (CA FC 1988). Wands states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention

The claims are drawn to a human CSA-1 polypeptide (SEQ ID NO.2), a polypeptide that is at least 50% identical to SEQ ID NO.2, the polypeptide comprising SEQ ID NO. 2. The invention is in a class of invention, which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The breadth of the claims

The claims are drawn to a polypeptide that is at least 50% identical to SEQ ID NO.2 and any polypeptides that comprise SEQ ID NO.2. The claims encompasses fragments and homologues of SEQ ID NO.2.

Quantity of experimentation

The quantity of experimentation in this area is extremely large since there is significant variability in the structure and effects of polypeptides that is at least 50% identical to SEQ ID NO.2 and that comprise SEQ ID NO.2. Moreover, it would require significant study to characterize the biological function of each of the sequences because the fragments and homologues of SEQ ID NO. 2 may not have the same biological functions as SEQ ID NO.2. The identification and characterization of each of these protein fragments and homologues would be inventive, unpredictable, and difficult in itself, requiring years of inventive effort with no guarantee of success in doing so.

One cannot extrapolate the teachings of the specification to the scope of the claims because the claims are broadly drawn to polypeptide fragments and homologues with or without the same biological properties of SEQ ID NO.2, and applicant has not enabled any polypeptides including SEQ ID NO.2 because it has not been shown that SEQ ID NO.2 or its fragments or homologues are differentially expressed in chondrosarcoma and normal cells.

The state of the prior art and the predictability or lack thereof in the art:

There is no art of record that discloses or suggests any activity for the claimed polypeptides.

The evidence in the specification provides that the nucleic acid (mRNA) that encodes the CSA-1 polypeptide (SEQ ID NO.2) is differentially expressed in chondrosarcoma and normal cells (see page 13, lines 26-29). While the specification discloses that the expression of CSA-1 in chondrosarcoma cells was localized to the

nucleus of the cells by immunostaining using a rabbit polyclonal antibody specific for a CSA-1 polypeptide (see page 17, lines 18-21), it fails to show that there is a differential expression of CSA-1 polypeptide in chondrosarcoma and normal cells. Moreover, one of skill in the art cannot extrapolate from the findings of mRNA expression to the expression of the protein. The specification has not taught one of skill in the art that the claimed polypeptide is in fact differentially expressed in chondrosarcoma and normal cells.

Those of skill in the art, recognize that expression of mRNA, specific for a tissue type, does not necessarily correlate nor predict equivalent levels of polypeptide expression. Greenbaum et al. (Genome Biology, 2003, Vol. 4, Issue 9, pages 117.1-117.8) cautions against assuming that mRNA levels are generally correlative of protein levels. The reference teaches (page 117.3, 2nd column) that primarily because of a limited ability to measure protein abundances, researchers have tried to find correlations between mRNA and the limited protein expression data, in the hope that they could determine protein abundance levels from the more copious and technically easier mRNA experiments. To date, however, there have been only a handful of efforts to find correlations between mRNA and protein expression levels, most notably in human cancers and yeast cells. And, for the most part, they have reported only minimal and/or limited correlations. The reference further teaches (page 117.4, 2nd column) that there are presumably at least three reasons for the poor correlations generally reported in the literature between the level of mRNA and the level of protein, and these may not be mutually exclusive. First, there are many complicated and varied post-transcriptional

mechanisms involved in turning mRNA into protein that are not yet sufficiently well defined to be able to compute protein concentrations from mRNA; second, proteins may differ substantially in their *in vivo* half lives; and/or third, there is a significant amount of error and noise in both protein and mRNA experiments that limit our ability to get a clear picture. The reference further notes (page 117.6, page 2nd column) that to be fully able to understand the relationship between mRNA and protein abundances, the dynamic processes involved in protein synthesis and degradation have to be better understood. For example, Alberts et al. (Molecular Biology of the Cell, 3rd edition, 1994, page 465) illustrate post-transcriptional regulation of ferritin wherein the translation of ferritin mRNA into ferritin polypeptide is blocked during periods of iron starvation. Likewise, if excess iron is available, the transferrin receptor mRNA is degraded and no transferrin receptor polypeptide is translated. Also, with regards to tumor associated antigens, Fu et al. (EMBO Journal, 1996, Vol. 15, pp. 4392-4401) teach that levels of p53 protein expression do not correlate with levels of p53 mRNA levels in blast cells taken from patients with acute myelogenous leukemia, said patients being without mutations in the p53 gene. Furthermore, Mallampalli et al. (Biochem. J. 1996, Vol. 318, pages 333-341) teach that the glucocorticoid, betamethasone, increased mRNA expression of cholinephosphate cytidylyltransferase (CT) as determined by RT-PCR and Southern analysis, but did not alter the levels of the CT enzyme as assayed by Western blotting (abstract, and page 339, 2nd column, 2nd paragraph). Thus, the predictability of protein translation and its possible utility as a diagnostic or therapeutic are not necessarily

contingent on the levels of mRNA expression due to the multitude of homeostatic factors affecting transcription and translation.

Because the mRNA expression does not always correlate the protein expression, and the specification fails to show that SEQ ID NO. 2 is differentially expressed in chondrosarcoma and normal cells, one skilled in the art would not know how to use SEQ ID NO. 2.

Moreover, claims are drawn to a polypeptide that is at least 50% identical to SEQ ID NO. 2 and a polypeptide that comprises SEQ ID NO. 2. One skilled in the art would recognize that these protein fragments and homologues would not have the same functions as SEQ ID NO.2. Furthermore, the instant specification does not teach that these polypeptides have the same functions as SEQ ID No.2

Protein chemistry is probably one of the most unpredictable areas of biotechnology. It is known in the art that the relationship between the amino acid sequence of a protein (polypeptide) and its tertiary structure (i.e. its binding activity) are not well understood and are not predictable (see Ngo et al., in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz, et al., (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495). There is no recognition in the art that sequence with identity predicts biological function. It is known in the art that even single amino acid changes or differences in a protein's amino acid sequence can have dramatic effects on the protein's function. For example, conservative replacement of a single “lysine” reside at position 118 of acidic fibroblast growth factor by “glutamic acid” led to the substantial loss of heparin binding, receptor binding and biological activity of the protein (Burgess et

al., J of Cell Bio. 111:2129-2138, 1990). In transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen (Lazar et al. Molecular and Cellular Biology 8:1247-1252, 1988). These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification will often dramatically affect the biological activity and characteristic of a protein. Furthermore, the specification fails to teach what deletions, truncations, substitutions and mutations of the disclosed sequence can be tolerated that will allow the protein to function as claimed. While it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with reasonable expectation of success are limited. Certain positions in the sequence are critical to the three-dimensional structure/function relationship, and these regions can tolerate only conservative substitutions or no substitutions. Residues that are directly involved in protein functions such as binding will certainly be among the most conserved (Bowie et al. Science, 247:1306-1310, 1990, p. 1306, col.2).

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure how to use any and all fragments with sequence similarity to the amino acid sequence shown in Fig. 1A (SEQ ID NO. 2).

Working examples:

The specification teaches how to make and purify CSA-1 polypeptide (SEQ ID NO. 2, see example 2) and how to generate antibodies specific for CSA-1 polypeptide (see example 3). The specification teaches that CSA-1 polypeptide is expressed in the nucleus of the chondrosarcoma cells (see page 17, lines 18-21). However, there in no data indicating that CSA-1 is indeed differentially expressed in chondrosarcoma and normal cells. Moreover, there is no data indicating that any of the fragments or homologues of SEQ ID NO. 2 are differentially expressed in chondrosarcoma and normal cells.

Guidance in the specification

While one of ordinary skill in the art can theoretically produce all of these proteins with art known techniques such as site-directed mutagenesis it would still be burdensome to one of ordinary skill in the art to produce all of these different combinations and thereafter determine their activity. It is art known that certain residues are shown to particularly important to the biological or structural properties of a protein or peptide, e.g., residues in active sites and such residues may not be generally be exchanged. Skolnick et al teach that sequence-based methods for function prediction are inadequate and knowing a protein's structure does not tell one its function (Skolnick, et al. Trends in Biotech. 18, 34-39, 2000, see abstract, in particular). Given the unlimited number of undisclosed polypeptides, there is insufficient working example demonstrating that any polypeptides including SEQ ID NO.2 are indeed differently expressed in chondrosarcoma and normal cells. Moreover, it is not clear what criteria

would be used in deciding which amino acids and how many of them would and could be substituted in SEQ ID NO. 2 such that the resulting polypeptide still have the same function as SEQ ID NO.2. Without such guidance, the changes which can be made in the protein structure and still maintain activity is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See Amgen Inc. V. Chugai Pharmaceutical Co. Lts., 18 USPQ2d 1016 and Ex parte Forman, 230 USPQ 546 (BPAI 1986). For these reasons, it would require undue experimentation of one skilled in the art to practice the claimed invention. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

Level of skill in the art

The level of the skill in the art is deemed to be high

Conclusion:

Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of the art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the presence of a working example which does not address the differential expression of the claimed polypeptides in chondrosarcoma and normal cells and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the

examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Claim Rejections - 35 USC § 112, 1st paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 7-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims are drawn to a CSA polypeptide and a polypeptide that is at least 50% identical to SEQ ID NO.2. The specification defines the CSA polypeptide as "a chondrosarcoma associated (CSA) polypeptide" and the term "chondrosarcoma associated" refers to the property of differential expression in chondrosarcoma cell compared to normal cartilage cells (see page 1, last paragraph and page 2, 1st paragraph). Therefore, the instant claims encompass any and all polypeptides that are differentially expressed in chondrosarcoma and normal cells. Moreover, the polypeptide that is at least 50% identical to SEQ ID NO.2 encompasses fragments and homologues. However, the written description in this case only sets forth one CSA polypeptide, i.e. CSA-1 (SEQ ID NO. 2), therefore the written description is not commensurate in scope with the claims which read on any and all polypeptides that are differentially expressed

in chondrosarcoma and normal cells, any and all fragments and homologues that are at least 50% identical to SEQ ID NO.2. The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

The claims are drawn to any and all polypeptide that are differentially expressed in chondrosarcoma and normal cells, any and all polypeptides that are at least 50% identical to SEQ ID NO.2. The specification discloses a single species for the genus, i.e. CSA-1 (SEQ ID NO.2). There is a lack of a written description regarding which amino acids within the full-length amino acid sequence of SEQ ID NO:2 that can be changed by deletion, addition, substitution and combination thereof such that the resulting fragments, or homologues that are at least 50% identical to SEQ ID NO.2 still have the same function as SEQ ID NO.2. Applicant does not appear to have reduced to practice any CSA polypeptides, any fragments or homologues of SEQ ID NO.2 except SEQ ID NO.2. Neither has applicant provided sufficient descriptive information such as definitive structural or functional features that are common to the genus of the

CSA polypeptides, and to the genus of the fragments and homologues of SEQ ID NO.2: That is, the specification provides neither a representative number of the CSA polypeptides, or the fragment or homologues nor does it provide a descriptive of structural features that are common to the CSA polypeptides, or the fragments and homologues of SEQ ID NO.2. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of a single species is insufficient to describe a highly variant genus. Because the genus of molecules encompassed by the term "a CSA polypeptide", or the fragments and homologues of SEQ ID NO.2 is extensive and the artisan would not be able to recognize that applicant was in possession of the invention as now claimed.

Consequently, Applicant was not in possession of the instant claimed invention. See Regents of the University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Adequate written description of genetic material "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. Id.

Therefore, only CSA-1 (SEQ ID NO. 2) but not the full breadth of "CSA polypeptide" or full breadth of the fragments and homologues of SEQ ID NO.2 meet the

written description provision of 35 U.S.C. § 112 first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claim 7 is rejected under 35 U.S.C. 102(e) as being anticipated by Draetta et al. (US Patent NO. 5,744,343, published on 4/28/1998, effective filing date 9/13/1994) as evidenced by Nawa et al. (Int. J. Cancer, 1996, 69(2): 86-91) and Dobashi et al. (Diag. Mol. Path, 1993, 2(4): 257-63, IDS).

Claim 7 is drawn to any substantially pure polypeptide that is CSA. CSA polypeptide is defined in the specification as "a chondrosarcoma associated (CSA)

polypeptide" and the term "chondrosarcoma associated" refers to the property of differential expression in chondrosarcoma cell compared to normal cartilage cells (see page 1, last paragraph and page 2, 1st paragraph).

Draetta et al. teach purified p53 protein (see column 48, example 2, lines 30-33). P53 protein is known in the art that is differentially expressed in chondrosarcoma and normal cells as evidenced by Nawa et al. (see title, abstract and Table 1) and Dobashi et al. (see page 261, left column). Therefore, Draetta et al. teach the claimed polypeptide.

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

Hong Sang
Art Unit: 1643
Jan. 5, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER